AREX®
BP 20 - 91125
PALAISEAU Cedex - FRANCE

Palaiseau, September 28th 2020

URGENT – FIELD SAFETY NOTICE

Information de modifications sur la notice et sur l'étiquette du HK2

Ref : **HK2**
AREX® FSN identifier : **FSN20200928**
AREX® FSCA identifier : **FSCA20200928**
Subject : **Modifications on the IFU and on the label of HK2**

For the attention of :
- Responsible of Materiovigilance
- Orthopedic surgeons
- Operating room supervisors
- Users of the medical device HK2

Affected device : HK2

Following a routine file review, we have identified some errors and missing information in the IFU and in the label of HK2.
References and batch numbers concerned :

- HK2 1.2 batch 12O366B
- HK2 1.5 batch 15O365B
- HK2 1.8 batch 18O359B
- HK2 1.2F batch 12Q456C
- HK2 1.5F batch 15P451C
- HK2 1.8F batch 18P450C

Details of errors and missing information :

- Word « Mini » added to the product name in the IFU ans in the label. The correct denomination recorded is « **Mini** external fixator HK2 ». The commercial reference remains unchanged
- Posbox « BP20 » removed of the AREX address in the IFU and in the label. The address of the ISO and CE certificates is the correct address of AREX site
- Logos added in the IFU and in the label
  -  (manufacturing date)
  -  (do not re-sterilize)
  -  (consult the Instruction for Use)
- Logo removed of the IFU
  -  (use by date)
- Clarifications on the cleaning protocol
- « Protocol A » (132°C) removed of the sterilization protocol

Risks linked to the errors and to the missing information
There is no risk concerning the HK2 components. They are conform.
We never had any customer claims or questions linked to the HK2 use.
Modifications were principally added to clarify some aspects of the notice and of the label before using the HK2 medical device :

- Corrections on the product denomination and on the address aim to be in phase with the data of AREX certificates
- The addition and the removal of logos illustrate the information detailled in the IFU, and avoid confusion liked to missing information
- The modifications on the cleaning protocol clarify the recommandations for the cleaning of the device
- The Sterilization protocol « B » remains unchanged and valid. However the protocol « A » was removed because that not correspond to the steam sterilization standards of the hospitals using the device

No major risk concerning product safety and performance was observed.

Actions to be implemented by the Distributor
Fill the sheet here below within 5 days.
Do not use the unpacked and/or sterilized units before acknowledge the new IFU and the new label.
Complete kits available in your stock will be returned to AREX for commercial exchange.

Actions carried out by AREX®
A communication was initially sent to all distrubutors and end customers of impacted HK2 batch numbers. We have requested to inventory their available stock ans to put them in quarantine until AREX instruction to follow.
AREX have corrected the IFU and the label of HK2. AREX available stock has been reprocessed to put in conformity all the stock for sale.
The IFU and the label will be send to customers by e-mail, to use them with the units already unpacked and/or sterilized. Complete kits returned to Arex will be exchanged with reprocessed kits.

Additional information and Technical Assistance
If you need further information or technical assistance regarding this notification, please contact our company at *01-69-41-22-12* or at *info@arex.fr*.

Baptiste LAROCHE
Quality Assurance and Regulatory Affairs Manager
AREX®

Formulaire to return by e-mail to AREX
info@arex.fr / baptiste.laroche@arex.fr

Name / First name :
Company / Service :
Country :

- If you have **complete HK2 kits** in your stock, please detail the quantity available :

Reference	Batch	Quantity
HK2 1.2	12O366B	
HK2 1.5	15O365B	
HK2 1.8	18O359B	
HK2 1.2F	12Q456C	
HK2 1.5F	15P451C	
HK2 1.8F	18P450C	

Kits impacted by this modification will be replaced. For that, thanks to return these quantities as soon as possible to the following address :

***AREX®** 3, allée du Clos Tonnerre – BP20*
91125 Palaiseau Cedex – FRANCE
info@arex.fr / 01-69-41-22-12

- If you have **« unpacked and/or sterilized » HK2 kits** in your stock, please detail the quantity of components available :

Référence	Lot du kit complet	Quantité broche	Quantité connecteur
HK2 1.2	lot 12O366B		
HK2 1.5	lot 15O365B		
HK2 1.8	lot 18O359B		
HK2 1.2F	lot 12Q456C		
HK2 1.5F	lot 15P451C		
HK2 1.8F	lot 18P450C		

These components **can only be used after read and understood the new IFU and teh new label.**

I certify that I have read and understood the modified documents (IFU ref IFU_HK2 Ed 01 and label ref v1-20200908) and have transmitted this information to the concerned healthcare professionals.

Date :
Signature :